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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,988	06/07/2006	Hiroshi Yamada	10873.1901USWO	1932

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EXAMINER	
HUANG, CHENG YUAN	
ART UNIT	PAPER NUMBER
4132	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,988	YAMADA ET AL.	
	Examiner	Art Unit	
	CHENG HUANG	4132	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7 June 2006 (Prelim. Amend.)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *7-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20060607, 20060828*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6, drawn to a medical tube.

Group II, claim(s) 7-10, drawn to a method of making a medical tube.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Evidence of lack of unity between the groups is found in Burns (U.S. Patent No. 5,370,655), wherein, as developed in the rejections set forth below, it is found to disclose the features of instant claim 1. Burns discloses a tube comprising polyimide resin and fluorine resin wherein the fluorine resin is on an inner face (Col. 2, lines 45-56). As such, the special technical features of the claimed invention are not found to define a contribution over the prior art.

3. During a telephone conversation with Douglas P. Mueller on 09/26/08 a provisional election was made with traverse to prosecute the invention of a medical tube, claims 1-6. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7-10 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

6. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Specification

7. The abstract of the disclosure is objected to because the abstract may not exceed 150 words in length. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Regarding claim 1, firstly, concerning the phrase "the face on which the fluorine resin particles melt and are precipitated ...", it is unclear as to on which face the fluorine resin particles precipitate when precipitation occurs on both the inner face and the outer face of the tube. It is unclear whether "the face" refers to both the inner face and the outer face, to either the inner face or the outer face, or to one particular face chosen between the two faces. Secondly, concerning the phrase "mixture component", it is unclear as to whether the tube is formed from the mixture component or whether by the claimed product-by-process limitations, the tube actually comprises the mixture component in final form.

11. Regarding claim 2, concerning the phrase "a tube made of a polyimide resin alone", it is unclear as to the characteristics of "a tube made of a polyimide resin alone." For example, this "a tube made of a polyimide resin alone" might be any tube of any

physical structure made from any process. It is unclear as to what requirements are necessary for this "a tube made of a polyimide resin alone."

12. Regarding claim 3, it is unclear as to what quantity the fluorine resin weight ratio is relative to. The fluorine resin weight percent may be relative to the total weight percent of fluorine and polyimide or the fluorine resin weight percent may be relative to only the polyimide weight percent. It is unclear what is the antecedent basis of the phrase "the content". Is this a description of the composition of the mixture?

Claim Rejections - 35 USC § 102/103

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claim 1, 2, and 4-6 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nakajima (JP 2003-340946).

17. Regarding claim 1, Nakajima teaches a tube comprising a polyimide resin and fluorine resin wherein the fluorine resin is on an inner face of the tube (Fig. 1, [0005]). The limitations "heated and cured" and "melt and are precipitated" are method limitations and do not determine the patentability of the product, unless the process necessarily results in articles that are structurally or compositionally distinguishable from those of the prior art. The claimed tube comprising polyimide resin and fluorine resin wherein melted fluorine resin is on an inner face, as claimed, would be expected to encompass the tube taught by Nakajima (Fig. 1, [0005]) since Nakajima discloses the claimed mixture composition wherein fluorine resin is disposed on an inner face of the tube. Therefore the prior art article would be expected to be identical to or substantially identical to those encompassed by the claim. The Applicant has failed to demonstrate that the claimed product-by-process limitations necessarily do not encompass the article of the cited art. Absent persuasive evidence a rejection is appropriate. MPEP 2113.

18. Further regarding claim 1, Nakajima is silent as to whether the face on which the fluorine resin particles are disposed is a low friction resistance face. However, it would be expected that the face on which the fluorine resin particles are present is inherently a low friction resistance face, since the fluorine resin material would be expected to confer

low frinction resistance characteristic. The polyimide and fluorine resin materials used by Nakajima are similar, if not identical, to those disclosed by the Applicant. Therefore, the face on which the fluorine resin particles melt and are precipitated would also be expected to be inherently a low friction resistance face.

19. Regarding claim 2, dependent on claim 1, Nakajima is silent as to a tube wherein a dynamic friction resistance of the inner face of the tube is 70% or less of that of a tube made of a polyimide resin alone. However, Nakajima teaches a tube wherein a fluororesin layer on the inner wall surface of a polyimide tube provides for improved sliding nature and chemical resistance of the inner wall surface [0003]. Particularly, provided that the Applicant's components for forming a polyimide resin in Example 4 are pyromellitic acid dehydrate and 4, 4' diaminodiphenyl ether and Applicant's choice of fluorine resin is polytetrafluoroethylene, these components are identical or substantially identical to Nakajima's Pyre-M. L., which is a combination of pyromellitic dianhydride and 4, 4' oxydianiline, and Nakajima's choice of fluorine resin of polytetrafluoroethylene. See for example the Materials Safety Data Sheet for RC5019 Pyre-M.L. Therefore, with identical or substantially identical materials the resulting tube of Nakajima would be expected to lead to values, in particular, of a dynamic friction resistance of the inner face of the tube, being 70% or less of that of a tube made of a polyimide resin alone, consistent to those of the claimed range and as given in Applicant's Table 1. Furthermore, since it is unclear as to the characteristics of "a tube made of a polyimide resin alone", it would be expected that, when a polyimide with high dynamic friction resistance is be the point of comparison, the dynamic friction resistance of the inner

face of the tube of Nakajima could readily satisfy the claimed requirement of 70% or less of that of especially high resistance tube made of a polyimide resin alone.

20. Regarding claim 4, dependent on claim 1, Nakajima teaches a tube wherein the tube comprises a polyimide resin formed from a precursor solution including at least one type of aromatic tetracarboxylic acid dehydrate and at least one type of aromatic diamine [0005]. The limitation "obtained by conversion to an imide by heating..." is a method limitation and does not determine the patentability of the product, unless the process necessarily results in articles that are structurally or compositionally distinguishable for those of the prior art. The implied structure of a tube comprising a polyimide resin formed from a precursor solution including at least one type of aromatic tetracarboxylic acid dehydrate and at least one type of aromatic diamine is taught by Nakajima [0005], where Nakajima teaches using Pyre-M.L. materials. Pyre-M.L. materials are aromatic polyimides formed from pyrometallic dianhydride and oxydianiline. See for example the Materials Safety Data Sheet for RC5019 Pyre-M.L. Therefore the articles of Nakajima are identical to or substantially identical to those claimed. Applicant has failed to demonstrate that the claimed product-by-process limitations necessarily do not give rise to articles that do not encompass the article of the cited art. Absent persuasive evidence a rejection is appropriate. MPEP 2113.

21. Regarding claim 5, dependent on claim 1, Nakajima teaches a tube wherein the fluorine resin particles are at least one selected from the group consisting of polytetrafluoroethylene (PTFE) [0005].

22. Regarding claim 6, dependent on claim 1, Nakajima teaches a tube wherein the tube is a catheter tube [0001].

23. Claim 1, 5, and 6 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Burns (U.S. Patent No. 5,370,655).

24. Regarding claim 1, Burns teaches a tube comprising a polyimide resin and fluorine resin wherein the fluorine resin is on an inner face (Col. 2, lines 45-56). The limitations "heated and cured" and "melt and are precipitated" are method limitations and do not determine the patentability of the product, unless the process necessarily results in articles that are structurally or compositionally distinguishable for those of the prior art. The claimed tube comprising polyimide resin and fluorine resin wherein melted fluorine resin is on an inner face, as claimed, would be expected to encompass the tube taught by Burns (Col. 2, lines 45-56) since Burns discloses the claimed mixture composition wherein fluorine resin is disposed on an inner face of the tube. Therefore the prior art article would be expected to be identical to or substantially identical to those encompassed by the claim. The Applicant has failed to demonstrate that the claimed product-by-process limitations necessarily do not encompass the article of the cited art. Absent persuasive evidence a rejection is appropriate. MPEP 2113.

25. Regarding claim 5, dependent on claim 1, Burns teaches a tube wherein the fluorine resin particles are at least one selected from the group consisting of polytetrafluoroethylene (PTFE) (Col. 4, lines 19-22).

26. Regarding claim 6, dependent on claim 1, Burns teaches a tube wherein the tube is a catheter tube (Col. 1, lines 13-15).

Claim Rejections - 35 USC § 103

27. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burns (U.S. Patent No. 5,370,655). Burns is relied upon as above with respect to the rejection of Claim 1. Burns does not teach the claimed weight ratio of Claim 3. However, Burns discloses that the inner face polyimide/PTFE should be lubricious and that PTFE contributes to this quality. See Burns (col. 3, line 50 through col. 4, line 25). It would have been obvious to one of ordinary skill in the art at the time of the invention to vary the relative amount of PTFE in this composition in order to optimize the desired degree of lubricity. It would be expected that a wide range of relative amounts would be explored in view of the routine experimentation required for this optimization and that compositions among those compositions explored would include those claimed.

Conclusion

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHENG HUANG whose telephone number is (571) 270-7387. The examiner can normally be reached on Monday-Thursday from 8 AM to 4 PM.

29. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL LAVILLA, can be reached on (571) 272-1539. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

30. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. H./

Examiner, Art Unit 4132

/Michael La Villa/
Michael La Villa
Supervisory Patent Examiner, Art Unit 4132
7 November 2008